Europass Curriculum Vitae

Personal information

First name(s) / Surname(s)	**GIANLUCA IGNAZZI**
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Nationality	Italian
Gender	Male

Desired employment / Occupational field

Clinical Trial Unit Lead

Work experience

Dates	December 2001 - ongoing
Occupation or position held	Clinical Trial Unit Lead - Clinical Trial Manager
Main activities and responsibilities	The Clinical Trial Manager is a key figure within the clinical study, he is the one who supervises the study itself and represents the control room of the entire research process. The operation is realized through the management of various work groups, interacting at various levels with most of the actors involved in a clinical study. He evaluates the feasibility of the study, is responsible for managing the study in its initial stages by preparing the documentation necessary for submitting the study to the regulatory and ethics committees. The Clinical Trial Manager also manages the contractual part relating to agreements with hospitals and any service providers (CRF, insurance, etc.). One of the key tasks at the start of the clinical study is the creation of specific study materials, manuals and procedures that are tailored to the needs of each individual study. He is also one of the active participants in the investigator meeting and in the Site Initiation Visit of the study. Manages the monitoring of the progress of the trial and the control of the integrity of the data collected, as well as the management of the drug and pharmacovigilance and management of the sites involved in the trial
Name and address of employer	I.S.G.Italian Sarcoma Group, Office of Dott. Orsi, Via Farini 31 – 40124, Bologna – Italy
Type of business or sector	Clinical Study

Dates	November 2019 – November 2021
Occupation or position held	Clinical Research Coordinator
Main activities and responsibilities	Responsible for coordinating the management activities of the clinical study at the experimental site. It is responsible for completing the feasibility questionnaires, interacts with Promoters and CROs for the management of the documentary material of the trial, collaborates with the Ethics Committee for the submission of documentation relating to the approval of the trial / amendment, budget and contract review, interfaces with the Ethics Committee for periodic monitoring of ongoing studies, management of the site's facilities (instrument calibration certificates, monitoring of correct functioning, collection of any temperature records), management of monitoring visits, coordinates the screening / randomization procedures of patients in collaboration with the medical staff, programs the specific procedures envisaged by the protocol, prepares the kits for centralized sampling and other specific study material and processes the laboratory samples relating to centralized sampling, manages the electronic systems for assigning the experimental drug (IVRS / IW RS), Manages the CRF, coordinates with the doctors of other Operating Units for all activities related to the clinical study, archives the material relating to the study, prepares the site for quality controls and inspections / audits, participates in the Investigators Meeting
Name and address of employer	A.O. Ordine Mauriziano, Ospedale Umberto I - S.C.D.U. Oncologia, Italy
Type of business or sector	Clinical Study

Dates	April 2011 – September 2019
Occupation or position held	Clinical Research Coordinator
Main activities and responsibilities	Responsible for coordinating the management activities of the clinical study at the experimental site. It is responsible for completing the feasibility questionnaires, interacts with Promoters and CROs for the management of the documentary material of the trial, collaborates with the Ethics Committee for the submission of documentation relating to the approval of the trial / amendment, budget and contract review, interfaces with the Ethics Committee for periodic monitoring of ongoing studies, management of the site's facilities (instrument calibration certificates, monitoring of correct functioning, collection of any temperature records), management of monitoring visits, coordinates the screening / randomization procedures of patients in collaboration with the medical staff, programs the specific procedures envisaged by the protocol, prepares the kits for centralized sampling and other specific study material and processes the laboratory samples relating to centralized sampling, manages the electronic systems for assigning the experimental drug (IVRS / IW RS), Manages the CRF, coordinates with the doctors of other Operating Units for all activities related to the clinical study, archives the material relating to the study, prepares the site for quality controls and inspections / audits, participates in the Investigators Meeting
Name and address of employer	A.O.U.Città della Salute e della Scienza di Torino, Presidio Molinette, Medical Oncology , COES (Hematology and Oncology Subalpine Center), Italy
Type of business or sector	Clinical Study
Dates	July 2009 – October 2009
Occupation or position held	Researcher in the proteomics laboratory
Main activities and responsibilities	Biologist
Name and address of employer	ASL Lecce - Laboratory of Proteomics, Clinical Oncology Hospital "Vito Fazzi", Italy
Type of business or sector	Clinical Research
Dates	May 2007 – October 2008
Occupation or position held	Research for thesis in molecular diagnostics
Main activities and responsibilities	Biologist
Name and address of employer	Sirs-Lab GmbH – Jena, Germany
Type of business or sector	Clinical Research

Education and training

Dates	2009 - 2010
Title of qualification awarded	First level Master in "Data Manager in Oncology: expert in the design and management of clinical trials"
Principal subjects/occupational skills covered	Design and management of clinical trials
Name and type of organisation providing education and training	University of Salento, Italy
Dates	2009
Title of qualification awarded	Qualification to the profession of Biologist
Dates	2006 - 2008
Title of qualification awarded	International Master's Degree in Biotechnology Medical Application
Principal subjects/occupational skills covered	Biotechnology Medical Application
Name and type of organisation providing education and training	University of Perugia, Italy

Level in national or international classification	Class 9 / S - D.M.270 / 04
Dates	1997 - 2008
Title of qualification awarded	Bachelor's Degree in Biology
Principal subjects/occupational skills covered	Biology
Name and type of organisation providing education and training	University of Salento, Italy
Level in national or international classification	Classe12 D.M.509/99
Dates	2020
Title of qualification awarded	“Good Clinical Practice and Study Management” Certification

Personal skills and competences

Mother tongue(s) **Italian**

Other language(s) **English**

Self-assessment

Understanding				Speaking				Writing	
Listening		Reading		Spoken interaction		Spoken production			
	Good		Good		Good		Good		Good

Organisational skills and competences	Replace this text by a description of these competences and indicate where they were acquired. (Remove if not relevant, see instructions)
Technical skills and competences	During laboratory experiences I gained techniques of cell cultures and molecular biology such as DNA and RNA extraction, reverse transcription, PCR and Real-Time PCR, agarose gel electrophoresis; proteomic techniques such as two-dimensional polyacrylamide gel electrophoresis (2D-PAGE), two-dimensional maps proteomic image analysis, MALDI-TOF mass spectrometry.
Computer skills and competences	Good knowledge of Windows and Microsoft Office
Other skills and competences	Involved in several phase II, III and IV, observational and medical devices clinical trials as Clinical Research Coordinator, in accordance with the ICH / GCP.
Driving licence	A and B

Additional information

Include here any other information that may be relevant, for example contact persons, references, etc. (Remove heading if not relevant, see instructions)

Annexes

List any items attached. (Remove heading if not relevant, see instructions)